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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,645	05/02/2006	Andre Lechot	PRE-SA-0157	3972
33751	7590	08/05/2010	EXAMINER	
Greatbatch Ltd. 10,000 Wehrle Drive Clarence, NY 14031			SCHAPER, MICHAEL T	
			ART UNIT	PAPER NUMBER
			3775	
			NOTIFICATION DATE	DELIVERY MODE
			08/05/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mscalise@greatbatch.com  
dkraft@greatbatch.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,645	<b>Applicant(s)</b> LECHOT ET AL.	
	<b>Examiner</b> MICHAEL T. SCHAPER	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 4-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,10-19,21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 Jul 08, 19 Feb 09, 1 Sept 09</u> .                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of species (2) in the reply filed on 4 Dec 2009 is acknowledged. The traversal is on the grounds that the groups are not distinct, due to an amendment done at the time of the restriction requirement. Since these are the only grounds of traversal and that these grievances have been alleviated by Applicant, the requirement is still deemed proper, the arguments deemed moot, and is therefore made FINAL.

Examiner further notes that the claimed subject matter to claims 7 and 9 are demonstrate that they should be withdrawn. As to claim 9, it is dependent on a claim identified as being withdrawn, thus being withdrawn. As to claim 9, the one-way catch mechanism reads on only species (1).

Thus, claims 2, 4-6, and 8 as well as claims 7 and 9 (now 2 and 4-9) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4 May 2010.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied

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with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/518,768 (hereinafter '768), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. '768 fails to disclose the collet connection as claimed in claim 11-19. Therefore, these claimed will be assigned the filing date of at least 26 Feb 2004.

### ***Response to Amendment***

Examiner notes that there is an amendment marking in claim 13 / line 10 assumedly left in from the amendment of 4 Dec 2009. Examiner requests that Applicant resolve this informality appropriately.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed subject matter concerning the prosthesis being connected to the apparatus by a drive train's prosthesis engaging thread (see claim 1 / line 9) or alternatively by a collet (claim 9 / lines 4-5) not part of the drive train renders the claim indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 10, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Parker et al. (US 2003/0050645).

Parker discloses an acetabular inserter (10, see FIGS. 1-3) for aiding a surgeon in controlling the installation of a hip prosthesis, the inserter comprising an inserter head (32); a housing (40) attached to the inserter head, the housing having at least one bend (see FIG. 1) permitting the housing to avoid anatomical structures or tissue during use in surgery and enclosing a drive train having (62), at a far end, a prosthesis engaging

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thread (30), and at the opposite end, a handle (12) which facilitates turning of the drive train by the operator; and a locking mechanism (60) associated with the housing which selectively locks the drive train, and thus the prosthesis, in position; wherein the inserter head is covered by an inserter head covering, made of a shock-absorbing material, in order to absorb the impact stresses incurred during use of the inserter (inherently); wherein the drive train includes at least one u-joint (34) located so as to transmit torque through a bend in the housing; wherein the housing is C-shaped in order to minimize the invasiveness of the surgery by better clearing anatomical structures and tissue (see FIG. 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (US 2003/0050645) in view of Hedley et al. (US 2005/0038443).

Parker discloses the claimed invention except for wherein the locking mechanism is an expandable collet which a knob, adjacent the handle, expands when turned in one direction so as to lock the collet against a surface of a prosthesis in order to prevent the prosthesis from rotation, thus enabling the surgeon to pre-set and lock the position of the prosthesis prior to the installation thereof; wherein the collet is comprises of two

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jaws having opposite ends pivoting on a fulcrum, one end of which being adapted to engage an interior surface of a prosthesis, the prosthesis engaging ends being drawn away from one another when a actuator piston, which passes through the fulcrum, is draw therebetween; wherein the fulcrum is mounted in a cage through which the actuator piston passes, the actuator piston having a shoulder bearing against a surface of the cage opposite the prosthesis engaging ends of the jaws, such that, as the actuator piston is being activated to separate the prosthesis engaging ends of the jaws, a shoulder of the piston contacting the surface compresses the jaws into the cage, thereby drawing the jaws into the inserter and, when connected to a prosthesis, thereby drawing the prosthesis against an impaction surface so as to firmly fix the prosthesis against the impaction surface; wherein the collet is provided with external, three-dimensional structures which engage with corresponding structures on the prosthesis; wherein the three dimensional structures are threads; wherein the three-dimensional structures are grooves; wherein the three-dimensional structures are divots.

Hedley discloses an acetabular implant inserter (900) wherein the locking mechanism is an expandable collet (925) which a knob (915), adjacent the handle, expands when turned in one direction so as to lock the collet against a surface of a prosthesis in order to prevent the prosthesis from rotation, thus enabling the surgeon to pre-set and lock the position of the prosthesis prior to the installation thereof (§33); wherein the collet is comprises of two jaws (925 / 925, see FIG. 11) having opposite ends pivoting on a fulcrum, one end of which being adapted to engage an interior surface of a prosthesis, the prosthesis engaging ends being drawn away from one

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another when a actuator piston (1000, see FIGS. 11 and 13), which passes through the fulcrum, is draw therebetween (§33); wherein the fulcrum is mounted in a cage (inner 920) through which the actuator piston passes, the actuator piston having a shoulder (see FIG. 13) bearing against a surface of the cage opposite the prosthesis engaging ends of the jaws, such that, as the actuator piston is being activated to separate the prosthesis engaging ends of the jaws, a shoulder of the piston contacting the surface compresses the jaws into the cage, thereby drawing the jaws into the inserter and, when connected to a prosthesis, thereby drawing the prosthesis against an impaction surface so as to firmly fix the prosthesis against the impaction surface (see FIG. 13, §40); wherein the collet is provided with external, three-dimensional structures which engage with corresponding structures on the prosthesis (see FIG. 12); wherein the three dimensional structures are threads / grooves / divots (see FIG. 12) for releasing the cup without having to move the tool body which prevents accidental dislodgement (see abstract).

At the time of invention, it would have been obvious to a person of ordinary skill in the art to have modified the device of Parker by substitution with an acetabular implant inserter wherein the locking mechanism is an expandable collet which a knob, adjacent the handle, expands when turned in one direction so as to lock the collet against a surface of a prosthesis in order to prevent the prosthesis from rotation, thus enabling the surgeon to pre-set and lock the position of the prosthesis prior to the installation thereof; wherein the collet is comprises of two jaws having opposite ends pivoting on a fulcrum, one end of which being adapted to engage an interior surface of a



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prosthesis, the prosthesis engaging ends being drawn away from one another when a actuator piston, which passes through the fulcrum, is draw therebetween; wherein the fulcrum is mounted in a cage through which the actuator piston passes, the actuator piston having a shoulder bearing against a surface of the cage opposite the prosthesis engaging ends of the jaws, such that, as the actuator piston is being activated to separate the prosthesis engaging ends of the jaws, a shoulder of the piston contacting the surface compresses the jaws into the cage, thereby drawing the jaws into the inserter and, when connected to a prosthesis, thereby drawing the prosthesis against an impaction surface so as to firmly fix the prosthesis against the impaction surface; wherein the collet is provided with external, three-dimensional structures which engage with corresponding structures on the prosthesis; wherein the three dimensional structures are threads / grooves / divots in view of Hedley for releasing the cup without having to move the tool body which prevents accidental dislodgement.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. SCHAPER whose telephone number is (571)270-7413. The examiner can normally be reached on M-F, 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. T. S./  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775